

Frequently Asked Questions: Participants

Q: What is the purpose of the NINDS Parkinson's Disease Biomarkers Program (PDBP)?

A: The NINDS PDBP is a study to identify biomarkers in Parkinson's disease which will allow researchers to evaluate the progression of Parkinson's disease in a more reliable, and faster way than is currently available. Currently, the only way to assess progression of Parkinson's disease is on physical examination. Biomarkers are essential to develop better clinical trials and treatments which will slow the progression of Parkinson's disease. That is, to develop treatments known as Neuroprotection treatments.

Q: What is a biomarker?

A: A biomarker is a measurable characteristic associated with a disease state. For example, blood pressure can be considered a biomarker, in the broadest sense, of heart disease. No such markers exist for Parkinson's disease, and there is a tremendous need for them in order to develop treatments which impact the actual biology of the disease. Right now, all we have are treatments that impact the symptoms.

Q: How many people will participate in the NINDS Parkinson's Disease Biomarkers Program (PDBP)?

A: Just over eight hundred people with Parkinson's disease (PD) and almost five hundred people who are healthy controls will be participating. There will also be people participating with related disorders (including Progressive Supranuclear Palsy and Multiple System Atrophy). Also, samples and data from people who have PD and have participated in other studies will be included in this project. This is the largest Parkinson's Disease Biomarkers project which the US Government has undertaken to date.

Q: What procedures do Participants undergo?

A: Participants undergo a neurological exam (evaluation of their Parkinson's disease as they would at a doctor's visit), some paper and pencil testing (of the thinking, memory, mood, and thought processes), smell testing (a "scratch and sniff test"). In some parts of the study, they will also undergo brain imaging studies. They will donate biological samples including blood (like you would give at the doctor's office), and cerebrospinal fluid (CSF) via lumbar puncture (LP). The entire visit will take most of the day.

Q: What is a Lumbar Puncture (LP)? Is it safe?

A: A lumbar puncture, or spinal tap, is an outpatient (in the office) procedure. This allows a small amount of cerebrospinal fluid, the fluid which bathes the brain and spinal cord, to be collected. During the procedure, a small needle (a bit thicker than a human hair) is gently inserted into the back, after numbing medicine is injected into the skin and muscle tissue. Then the fluid is gently withdrawn. After that, the needle is withdrawn. It is a straightforward procedure with a low risk. Some people experience headache after the procedure. In order to reduce the risk of headache, a caffeinated beverage and increased fluid intake, as well as lying down as much as possible is often recommended. Your doctor will have specific advice regarding what you should do after a lumbar puncture. The entire procedure takes about half an hour.

Before you have a lumbar puncture, you must tell your doctor if you are on any blood thinning medications, including aspirin, and if you have ever had any problems with excessive bleeding. Also, let your doctor know if you are pregnant.

Q: What is done with the information collected during the study?

A: The information collected in the study is given a unique identifier (i.e., a code) so that your name and identity are hidden to everyone but your doctor and their team. Then, this information is banked in the Data Management Resource (DMR) for the Parkinson's Disease Biomarkers Program (PDBP). The biological specimens (blood samples, cerebrospinal fluid) are banked in a de-identified (anonymous) way at the National Institute of Neurological Disorders and Stroke (NINDS) Repository. The NINDS Repository has been in existence since 2001, and has banked samples from over 30 thousand people.

Investigators from academic institutions and industry (scientists) can submit a request to use the data and the samples for their research projects. They will have to write an application that is reviewed at the NIH and by experts, to assure that their project is feasible (possible) and likely to be of benefit to the discovery of biomarkers and treatments for Parkinson's disease. People who use these data or samples will be required to share their data further with other researchers, and to let the DMR know what their results are. We plan to post these results so that participants and others can be made aware of them, on this public website.

Q: Can I access the database?

A: Data access is currently not available to participants or the general public. However, we are hoping that upgrades during 2014 will include public access to summary data. Individuals who participated in one of the PDBP research projects will not be able to access their own individual data, because all data in the PDBP is anonymized. If you are a PDBP participant and you have questions about your test results, please discuss them with the investigator who is responsible for the study you participated in.